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JUL 2 6 2000

K002033

BD

Indispensable to human health

SPECIAL PREMARKET NOTIFICATION
[510(k)] Summary

Submitter:	Becton Dickinson Infusion Therapy Systems Inc.
Address:	9450 South State Street Sandy, UT 84070
Contact Person:	Leslie Wood Manager, Regulatory Affairs
Telephone Number:	(801) 565-2504
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Date Summary Prepared:	June 30, 2000
Trade Name:	Insyte™ Autoguard™-P
Common Name:	Intravascular Catheter
Classification Name:	Intravascular Catheter
Unmodified/Predicate Device:	Insyte™ Autoguard™ K880260, K952861, K971339

Description of the Insyte™ Autoguard™-P device:

Becton Dickinson currently markets the Insyte™ Autoguard™ catheter that includes a needle-shielding component. After threading the catheter into the vein, the user must press a button to retract the needle into a cylindrical needle shield.

The Insyte™ Autoguard™-P is the modified version of this product that allows the needle to retract into the cylindrical needle shield after use without any additional action by the user to activate the sharps safety feature.

Intended Use of the Insyte™ Autoguard™-P device:

[21 CFR Part 880--GENERAL HOSPITAL AND PERSONAL USE DEVICES General Hospital and Personal Use Therapeutic Devices Sec. 880.5200 and 880.5440]

An intravascular catheter is a device that consists of a slender tube and any necessary connecting fittings and that is inserted into the patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravenously. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure.

Technological Characteristics Comparison:

Both the current and modified devices use the same spring retraction technology to provide the force necessary to retract the needle into the needle-shielding component. The difference between the current and modified devices is that the current product requires the user to press a button to active the needle-shielding component while the needle-shielding component is passively activated in the modified device.

Nonclinical Tests Support Substantial Equivalence:

The following qualities of the two devices are the same and support substantial equivalence: Indications for use, fundamental scientific technology, materials used in the needle-shielding component, Insyte™ catheter made with Vialon™ material, needle geometry, visualization of blood return, overall size, and potential for blood exposure during use.

Conclusions from Nonclinical Tests:

The modified device, Insyte™ Autoguard™-P is substantially equivalent to the currently marketed Insyte™ Autoguard™ device.

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 6 2000

Ms. Leslie Wood
Manager, Regulatory Affairs
BD Medical Systems
9450 South State Street
Sandy, Utah 84070

Re: K002033
Trade Name: BD Insyte Autoguard -P and BD Insyte Autoguard -P Winged Intravascular Catheters
Regulatory Class: II
Product Code: FOZ
Dated: June 30, 2000
Received: July 5, 2000

Dear Ms. Wood:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Becton Dickinson Infusion Therapy Systems Inc.
Sandy, UT 84070

INDICATIONS FOR USE

510(k) Number: *K002033*

Device Proprietary Name: BD Insyte™ Autoguard™ - P Intravascular Catheter

Device Classification Name: Intravascular Catheter (80 FOZ)

Indications for Use:

As indicated in 21 CFR Part 880.5200, to sample blood, monitor blood pressure, or administer fluids intravenously. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy, appropriateness for the solution being infused, and duration of therapy.

The BD Insyte™ Autoguard™-P catheters provide a shielding mechanism intended to reduce the incidence of accidental needle sticks. When the catheter hub and needle assembly components are separated, the needle retracts into the needle-shielding barrel automatically.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use: _____

(Division Sign-Off)
Division of **Dental, Infection Control,** and General **Hospital Devices**
510(k) Number K002033